IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MAYNE PHARMA LLC, Plaintiff, v. PERRIGO ISRAEL PHARMACEUTICALS LTD. and PERRIGO CO. PLC, Defendant.	C.A. No. _____

COMPLAINT

Plaintiff Mayne Pharma LLC ("Mayne" or "Plaintiff"), by its undersigned attorneys, brings this action against Defendants Perrigo Israel Pharmaceuticals Ltd. and Perrigo Company plc (collectively, "Perrigo" or "Defendants"), and hereby alleges as follows:

NATURE OF ACTION

1. This is an action for patent infringement of U.S. Patent No. 10,857,159 (the "'159 patent" or "patent-in-suit") under the patent laws of the United States, Title 35, United States Code § 100, *et seq*. This action arises from Perrigo's submission of Abbreviated New Drug Application ("ANDA") No. 215266 to the U.S. Food and Drug Administration ("FDA"). Through its ANDA, Perrigo seeks approval to market 0.05% halobetasol propionate topical foam, a generic version of Mayne's LEXETTE® drug product ("Perrigo ANDA product"), prior to the expiration of the patent-in-suit.

2. This is also an action under 28 U.S.C. §§ 2201–02 for a declaratory judgment of patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. §§ 271(a), (b), and/or (c).

THE PARTIES

3. Mayne is a Delaware limited liability company with a place of business at 1240 Sugg Parkway, Greenville, North Carolina 27834.

4. Upon information and belief, Perrigo Israel Pharmaceuticals Ltd. ("Perrigo Israel") is an Israeli corporation with a place of business at 1 Rakefet St., Shoham 608500, Israel.

5. Upon information and belief, Perrigo Company plc ("Perrigo Ireland") is an Irish corporation with a place of business at The Sharp Building, Hogan Place, Dublin 2, Ireland.

6. Upon information and belief, Perrigo Israel is a wholly-owned subsidiary by Perrigo Ireland.

7. Upon information and belief, Perrigo prepared and submitted ANDA No. 215266 and continues to collaborate in seeking FDA approval of that application.

8. Upon information and belief, Perrigo intends to commercially manufacture, market, offer for sale, and sell the Perrigo ANDA product throughout the United States, including in the State of Delaware, in the event the FDA approves ANDA No. 215266.

9. Upon information and belief, Perrigo Israel manufactures, sells, markets, and distributes generic pharmaceutical products throughout the United States, including in this district, in conjunction with or under the direction of Perrigo Ireland.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338, 2201, 2202 because this is a patent infringement action that arises under the patent laws of the United States, 35 U.S.C. § 100 *et seq.* and the Declaratory Judgment Act.

11. This Court has personal jurisdiction over Perrigo Israel because, *inter alia*, it has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Perrigo Israel

develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in Delaware and therefore transacts business within Delaware related to Mayne's claims, and/or has engaged in systematic and continuous business contacts within Delaware.

12. This Court has personal jurisdiction over Perrigo Ireland because, *inter alia*, Perrigo Ireland, itself and through its wholly-owned subsidiary Perrigo Israel, has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Perrigo Ireland regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware either directly or indirectly through affiliated companies. Upon information and belief, Perrigo Ireland derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware. In addition, Perrigo Ireland is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Perrigo Israel and therefore the activities of Perrigo Israel in this jurisdiction can be attributed to Perrigo Ireland.

13. This Court has jurisdiction over Perrigo because, *inter alia*, Perrigo has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Mayne, a Delaware limited liability company, in Delaware. For example, on information and belief, following approval of ANDA No. 215266, Perrigo will make, use, import, sell, and/or offer for sale the Perrigo ANDA product in the United States, including in Delaware, prior to the expiration of the patent-in-suit.

14. Perrigo reported in its 2020 Annual Report its "customers include major global, national, and regional retail drug, supermarket, and mass merchandise chains such as Walmart,

Costco, CVS, Target, Walgreens Boots Alliance, Kroger, Dollar General, Sam's Club, Topco, e-commerce stores including Amazon, and major wholesalers, including McKesson, Amerisource Bergen, and Cardinal Health." Upon information and belief, Perrigo intends to sell the Perrigo ANDA product through these same retail outlets in Delaware, such as Walmart, Costco, CVS, Target, Walgreens, Dollar General, and Sam's Club.

15. Upon information and belief, Perrigo will market and distribute its Perrigo ANDA product in Delaware, and this product will be prescribed by physicians practicing in this state, and dispensed by pharmacies located in this state, all of which would have a substantial effect on commerce.

16. Upon information and belief, Perrigo is part of a corporate family that includes at least twenty-two Delaware entities, which are incorporated in Delaware. Upon information and belief, the Perrigo corporate family as a whole relies on Delaware for its successful business operations.

17. Upon information and belief, Perrigo Ireland works in concert with its subsidiary Perrigo Israel to sell, market, and distribute its generic drugs in the United States, including in this district.

18. Perrigo Ireland has previously been involved in litigations brought in this judicial district, for example, in *Anacor Pharmaceuticals, Inc. v. Ascent Pharmaceuticals, Inc. et al.*, No. 18-cv-1673-RGA (D. Del.); and *In re: Kerydin (Tavaborole) Topical Solution 5% Patent Litigation*, No. 19-md-02884-RGA (D. Del.).

19. Perrigo Israel has previously consented to suit in this judicial district and has availed itself of a Delaware court through the assertion of counterclaims in lawsuits brought in Delaware, for example, in *Taro Pharmaceuticals U.S.A., Inc. et al. v. Perrigo Israel*

Pharmaceuticals Ltd., No. 14-cv-989-RGA (D. Del.); *Sun Pharmaceutical Industries, Inc. et al. v. Perrigo Company et al.*, No. 18-cv-703-CFC (D. Del.); *Stiefel Research Australia Pty. Ltd. v. Perrigo Co. & Perrigo Israel Pharmaceuticals, Ltd.*, No. 09-cv-758-JJF (D. Del.); *Stiefel Laboratories, Inc. et al. v. Perrigo Israel Pharmaceuticals Ltd. & Perrigo Co.*, No. 10-cv-592-GMS (D. Del.); and *Unimed Pharmaceuticals LLC et al. v. Perrigo Co. & Perrigo Israel Pharmaceuticals Ltd.*, No. 13-cv-236-LPS (D. Del.). Perrigo Israel has further been involved in several litigations in this judicial district, including, for example, *KV Pharmaceutical Co. et al. v. Perrigo Israel Pharmaceuticals Ltd. et al.*, No. 10-cv-641-SLR (D. Del.); *Unimed Pharmaceuticals, LLC et al. v. Perrigo Co. et al.*, No. 14-cv-985 (D. Del.); *Unimed Pharmaceuticals, LLC et al. v. Perrigo Co. et al.*, No. 14-cv-1003 (D. Del.).

20. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

21. Venue is also proper in this District under 28 U.S.C. § 1391(c)(3) because on information and belief, Perrigo Israel is an Israeli corporation and Perrigo Ireland is an Irish company and both are not residents in the United States.

THE PATENT-IN-SUIT

22. The ’159 patent, titled “Halobetasol Foam Composition and Method of Use Thereof,” was duly and legally issued by the United States Patent and Trademark Office (“PTO”) on December 8, 2020, to Robert T. Gauthier and James D. Hammer. Mayne Pharma, LLC, is listed as the assignee and is currently the sole assignee of the ’159 patent.

23. A true and correct copy of the ’159 patent is attached as Exhibit A.

PERRIGO'S INFRINGEMENT OF THE PATENT-IN-SUIT

24. By a letter dated March 16, 2021, Perrigo Israel notified Mayne that Perrigo had submitted ANDA No. 215266 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) ("Perrigo Notice Letter").

25. The Perrigo Notice Letter provides that Perrigo Israel submitted ANDA No. 215266 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a generic version of LEXETTE prior to the expiration of the patent-in-suit. Upon information and belief, Perrigo intends to engage in the commercial manufacture, use, and sale of the Perrigo ANDA Product, directly or indirectly.

26. By filing ANDA No. 215266, Perrigo Israel has necessarily represented to the FDA that the Perrigo ANDA product has the same active ingredient, the same dosage form, and the same strength as LEXETTE and that the Perrigo ANDA product is bioequivalent to LEXETTE. Upon information and belief, Perrigo further intends to market its ANDA product for the same indication as LEXETTE: topical treatment of plaque psoriasis in patients 18 years of age and older.

27. The Perrigo Notice Letter provides that the '159 patent is unenforceable, invalid, and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the Perrigo ANDA product and that Perrigo Israel has included a Paragraph IV certification in its ANDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

28. The Perrigo Notice Letter further contained a purported detailed statement of the factual and legal basis for its Paragraph IV certification.

29. In the Perrigo Notice Letter, Perrigo Israel offered confidential access to portions of its ANDA No. 215266, in specific terms and conditions set forth in the Offer of Confidential Access ("OCA") included in the Perrigo Notice Letter. Perrigo Israel requested that Mayne accept

the OCA before receiving access to its ANDA. The OCA contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the OCA limited access to a single outside law firm. Further, the OCA included a broad patent prosecution bar, which did not have a carve out for *inter partes* review. The OCA further unreasonably prohibited Mayne from disclosing information to outside scientific consultants or other outside counsel. The requirements Perrigo Israel placed on access to ANDA No. 215266 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which provides that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." The parties discussed modifying the OCA but ultimately were unable to reach an agreement that would provide sufficient time to review the ANDA.

30. Upon information and belief, the Perrigo ANDA product is covered by the claims of the '159 patent.

31. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of Mayne's receipt of the Perrigo Notice Letter.

COUNT I
(Infringement of the '159 Patent)

32. Mayne re-alleges and incorporates by reference paragraphs 1 through 31 as if fully alleged herein.

33. Perrigo's submission of ANDA No. 215266 to the FDA under section 505(j) of the U.S. Federal Food, Drug, and Cosmetic Act to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Perrigo ANDA product prior to the expiration of the

'159 patent constitutes a technical act of infringement of at least one of the claims of the '159 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(e)(2)(A).

34. Unless enjoined by the Court, upon FDA approval of Perrigo's ANDA No. 215266, upon information and belief, Perrigo will infringe one or more claims of the '159 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, and selling the Perrigo ANDA product in the United States and/or importing said product into the United States, and/or by actively inducing and contributing to infringement of the '159 patent by others.

35. If Perrigo's marketing and sale of the Perrigo ANDA product prior to expiration of the '159 patent and all other relevant exclusivities are not enjoined, Mayne will suffer substantial and irreparable harm for which there is no remedy at law.

36. Perrigo had actual and constructive notice of the '159 patent prior to filing ANDA No. 215266 and was aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '159 patent would constitute an act of infringement of the '159 patent. Perrigo had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the Perrigo ANDA product will not contribute to the infringement of and/or induce the infringement of the '159 patent.

37. Perrigo's Detailed Statement in the Notice Letter lacks any sufficient contention that the Perrigo ANDA product will not infringe, contribute to the infringement of, or induce the infringement of the '159 patent.

38. In addition, Perrigo filed ANDA No. 215266 without adequate justification for asserting the '159 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Perrigo ANDA product. Perrigo's conduct in

certifying invalidity, unenforceability, and/or non-infringement with respect to the '159 patent renders this case "exceptional" under 35 U.S.C. § 285.

39. Mayne will be irreparably harmed if Perrigo is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '159 patent. Mayne does not have an adequate remedy at law, and considering the balance of hardships between Mayne and Perrigo, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II
(Declaratory Judgment of Infringement of the '159 Patent)

40. Mayne re-alleges and incorporates by reference paragraphs 1 through 39 as if fully alleged herein.

41. Mayne's claims also arise under the Declaratory Judgment Act, in the State of Delaware, by or through Perrigo and its affiliates.

42. The commercial manufacture, use, offer to sell, or sale of the Perrigo ANDA product prior to the expiration of the '159 patent will constitute direct infringement of one or more claims of the '159 patent under 35 U.S.C. § 271(a).

43. On information and belief, Perrigo knows that health care professionals or patients will use the Perrigo ANDA product in accordance with the labeling sought by ANDA No. 215266, and Perrigo will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '159 patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

44. On information and belief, Perrigo's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the Perrigo ANDA product complained of

herein will begin immediately after the FDA approves the ANDA No. 215266. Any such conduct before the '159 patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '159 patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

45. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Mayne and Perrigo concerning liability for the infringement of the '159 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

46. Mayne will be substantially and irreparably harmed by Perrigo's infringing activities unless those activities are enjoined by this Court. Mayne may not have adequate remedy at law.

47. This case is exceptional, and Mayne is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Mayne respectfully requests the following relief:

A. A judgment that the claims of the '159 patent are not invalid, are not unenforceable, and are infringed by Perrigo's submission of ANDA No. 215266 under 35 U.S.C. § 271(e)(2)(A);

B. A declaratory judgment that the claims of the '159 patent are not invalid, are not unenforceable, and that Perrigo's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the Perrigo ANDA product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '159 patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

C. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Perrigo, its affiliates and subsidiaries, and all persons and entities acting in concert with Perrigo from commercially manufacturing, using, offering for sale, selling, or importing any product that infringes the '159 patent, including the Perrigo ANDA product;

D. The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 215266 shall be no earlier than the expiration date of the '159 patent, or any later expiration of exclusivity for the '159 patent, including any extensions or regulatory exclusivities;

E. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Perrigo engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the Perrigo ANDA product, or any product that infringes the '159 patent, or induces or contributes to such conduct, prior to the expiration of the '159 patent;

F. The entry of judgment declaring that Perrigo's acts render this case an exceptional case, and awarding Mayne its attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

G. An award to Mayne of its costs and expenses in this action; and

H. Such other and further relief as the Court may deem just and proper.

Dated: April 29, 2021

K&L GATES LLP

/s/ Steven L. Caponi

Steven L. Caponi (No. 3484)
Matthew B. Goeller (No. 6283)
600 N. King Street, Suite 901
Wilmington, DE 19801
Phone: (302) 416-7080
steven.caponi@klgates.com
matthew.goeller@klgates.com

Counsel for Mayne Pharma LLC